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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20752

Re: Draft Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, September 2004, submitted to Docket #2004-22206

Pfizer recognizes the great effort and forethought the FDA has put forth in the publication of the draft guidance and appreciates the opportunity to provide comments to further clarify and strengthen the proposed guideline.

Please find our specific comments in the attached Spreadsheet (Attachment 1) and the following general comments:

Item A: Transitioning from Compliance Systems to Quality Systems
Achieving quality is defined in this document as "achieving identity, strength, purity, and other quality characteristics designed to assure the required levels of safety and effectiveness". Where robust quality systems are in place, the dependence on end product testing becomes diminished. The definition of quality and achieving quality should be based instead on the quality systems and process knowledge that predict the above mentioned characteristics as well as availability and patients requirements. Quality then progresses into a more probabilistic definition. This will necessitate transitioning from compliance systems to quality systems. For example, trending of data is identified as an important element of a good quality system. However, much of the data collected is for compliance systems and can not be meaningfully trended.

Item B: Change Management as opposed to Change Control (line 708)
In an environment supportive of a quality systems approach rather than a quality control approach, it is necessary to describe change management in lieu of change control. Change in the current pharmaceutical environment can no longer be considered in isolation as a single event. Rather, the result of change has many different impacts such as training, validation, stability, and regulatory compliance. Prior to implementing, and as part of assessing a change, a site must understand all these aspects and their interactions and consequences. This understanding occurs as a site increases its process knowledge. A site can not review a specific change without evaluating all the impacted and interacting systems.